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Paper #2

SHEET 1 OF 2

FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT & TRADEMARK OFFICE	ATTY DOCKET NO. ALLIA.228A	APPLICATION NO. 09/919,477
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	APPLICANT Bot et al.	
	FILING DATE 30 July 2001	GROUP Unknown 1644

										U.S. PATENT DOCUMENTS			
EXAMINER INITIAL	D N	O U	C M	U B	M E	E R	N	T	DATE	NAME	CLASS	SUBCLASS	FILING DATE
Sul	5	7	1	4	1	4	1		2/1998	Ho et al.	—	—	1 Jun 1995
	5	7	7	0	2	3	4		6/1998	Gristina et al.	—	—	13 Dec 1996
	5	9	2	8	6	4	7		7/1999	Rock	—	—	15 Sep 1995
	5	9	7	7	0	8	1		11/1999	Marciani	—	—	20 May 1998

										FOREIGN PATENT DOCUMENTS				
EXAMINER INITIAL	D N	O U	C M	U B	M E	E R	N	T	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO	
Sul ↓	9	9	4	4	5	8	3		9/1999	WO	—	—		
	0	0	6	1	1	5	7		10/2000	WO	—	—		
	0	1	2	6	6	8	3	A2	4/2001	WO	—	—		
	0	1	7	4	7	5	9	B1	4/1991	EP	—	—		

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)													
Sul	1.	Andya, James D. et al. <i>The Effect of Formulation Excipients on Protein Stability and Aerosol Performance of Spray-Dried Powders of a Recombinant Humanized Anti-IgE Monoclonal Antibody</i> , 16(3) <i>Pharmaceutical Res.</i> , pp 350-358 (1999).												
	2.	Bustami, Rana T. et al. <i>Generation of Micro-Particles of Proteins for Aerosol Delivery Using High Pressure Modified Carbon Dioxide</i> , 17(11) <i>Pharmaceutical Res.</i> , pp 1360-1366 (2000).												
	3.	Bosquillon, Cynthia et al. <i>In Uence of Formulation Excipients and Physical Characteristics of Inhalation Dry Powders on their Aerosolization Performance</i> , 70 <i>J. of Controlled Release</i> , pp 329-339 (2001).												
	4.	Christensen, K. L. et al, <i>Preparation of Redispersible Dry Emulsions by Spray Drying</i> , 212 <i>Int. J. of Pharmaceutics</i> , pp 187-194 (2001).												
	5.	Costantino, Henry R., et al. <i>Effect of Mannitol Crystallization on the Stability and Aerosol Performance of a Spray-Dried Pharmaceutical Protein, Recombinant Humanized Anti-IgE Monoclonal Antibody</i> , 87(11) <i>J. of Pharmaceutical Sciences</i> , pp 1406-1411 (Nov. 1998).												
	6.	Haitsma, Jack J., et al. <i>Exogenous Surfactant as a Drug Delivery Agent</i> , 47 <i>Advanced Drug Delivery Reviews</i> , pp 197-207 (2001).												
	7.	Johansen, Pål, et al. <i>Technological Considerations Related to the Up-Scaling of Protein Microencapsulation b Spray-Drying</i> , 50 <i>European J. of Pharmaceutics and Biopharmaceutics</i> , pp 413-417 (2000).												

EXAMINER David A. Samuels	DATE CONSIDERED 2/6/04
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED, INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.	

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										FOREIGN PATENT DOCUMENTS			
EXAMINER INITIAL	D N	O U	C M	U B	M E	E R	N	T	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION YES NO

EXAMINER INITIAL		OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
See	8	Johnson, Keith A., <i>Preparation of Peptide and Protein Powders for Inhalation</i> , 26 <i>Advanced Drug Delivery Reviews</i> , pp 3-15 (1997). ✓
	9	Millqvist-Fureby, Anna, et al. <i>Spray-Drying of Trypsin - Surface Characterisation and Activity Preservation</i> , 188 <i>Int. J. of Pharmaceutics</i> , pp 243-253 (1999). ✓
	10	Mitra, Ranjana et al., <i>Enhanced Pulmonary Delivery of Insulin by Lung Lavage Fluid and Phospholipids</i> , 217 <i>Int. J. of Pharmaceutics</i> , pp 25-31 (2001). ✓
	11	Moghim, S. Moein et al., <i>Recognition by Macrophages and Liver Cells of Opsonized Phospholipid Vesicles and Phospholipid Headgroups</i> , 18(1) <i>Pharmaceutical Res</i> , pp 1 - 8 (2001). ✓
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	13	Santinho, Ana J.P., et al., <i>Influence of Formulation on the Physicochemical Properties of Casein Microparticles</i> , 186 <i>Int. J. of Pharmaceutics</i> , pp 191-198 (1999). ✓
	14	Schöler N., et al., <i>Surfactant, But Not The Size Of Solid Lipid Nanoparticles (SLN) Influences Viability And Cytokine Production Of Macrophages</i> , 221 <i>Int. J. of Pharmaceutics</i> pp 57-67 (2001). ✓
	15	Todo, Hiroaki et al., <i>Effect of Additives on Insulin Absorption From Intratracheally Administered Dry Powders in Rats</i> , 220 <i>Int. J. of Pharmaceutics</i> , pp 101-110 (2001). ✓
	16	Trolle, S. et al., <i>In Vivo Fate and Immune Pulmonary Response After Nasal Administration of Microspheres Loaded with Phosphorylcholine-Thyroglobulin</i> 183 <i>Int. J. of Pharmaceutics</i> pp 73-79 (1999). ✓
↓	17	Williams III, R.O. et al. <i>Formulation of a Protein with Propellant HFA 134a for Aerosol Delivery</i> , 7 <i>European J. of Pharmaceutical Sciences</i> , pp 137-144 (1998).

EXAMINER David A. Saunders	DATE CONSIDERED 2/6/04
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SHEET 7 OF 1

FORM PTO-1449

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICE

ATTY. DOCKET NO.
ALLIA.228A

APPLICATION NO.
09/919,477

INFORMATION DISCLOSURE STATEMENT
BY APPLICANT

APPLICANT
Bot, et al.

FILING DATE
July 30, 2001

GROUP
Unknown 1644

(USE SEVERAL SHEETS IF NECESSARY)

U.S. PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE (IF APPROPRIATE)

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO

EXAMINER
INITIAL

OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)

Day	1.	Avrameas, et al., <i>Eur. J. Immunol.</i> , 26:394-400, 1996
	2.	Bach, J.F., <i>Endocr. Rev.</i> , 1994
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	7.	Gower's Handbook of Industrial Surfactants 1993, Pages 885-904
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	9.	Kimpimaki, et al., <i>J. Clin. Endocrinol. Metab.</i> , 85:1126-1132, 2000
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	12.	Prigozy, et al., <i>Immunity</i> , 6:187-197, 1997
	13.	Reise Sousa, et al., <i>J. Exp. Med.</i> , 178:509-517, 1993
	14.	Roll, et al., <i>Diabetes</i> , 45:967-943, 1996
	15.	Schlesinger, L. S., <i>J. Immunol.</i> , 150:2920-2930, 1993
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	17.	Stahl, P.D., <i>Curr. Opin. Immunol.</i> , 4:49-72, 1992
	18.	Wilson and Pearson, <i>J. Immunol.</i> , 136:4681-4688, 1986
	19.	Yamamoto, et al., <i>Infect. Immun.</i> , 65:1077-1082, 1997

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EXAMINER

Daniel A. Sennrich

DATE CONSIDERED

2/6/04

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) Sheet 1 of 1		Complete if Known	
		Application Number	09/919,477
		Filing Date	07/30/2001
		First Named Inventor	Adrian Bot et al.
		Group Art Unit	1614
		Examiner Name	Unassigned
		Attorney Docket Number	0157.00

OTHER PRIOR ART – NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
Jhl	AI	NEWMAN, "Ovalbumin peptide encapsulated in poly(d,l lactic-co-glycolic acid) microspheres is capable of inducing a T helper type 1 immune response," J. Cont. Rel., p. 49-59,	
	AJ	AMSELEM, "Polymeric Biodegradable Lipospheres as Vaccine Delivery Systems," Poly. for Adv. Tech., p. 351-357,	
	AK	ALONSO, "Determinants of Release Rate of Tetanus Vaccine from Polyester Microspheres," Pharm. Res., p. 945-953,	
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	AM	EDWARDS, "Large Porous Particles for Pulmonary Drug Delivery," Science, p. 1868-1871,	
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	AO	JEFFERY, "The preparation and characterization of poly(lactide-co-glycolide) microparticles. II. The entrapment of a model protein using a (water-in-oil)-in-water emulsion solvent evaporation technique," Pharm. Res., p. 362-368,	
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AS	BOT, "Receptor-Mediated targeting of spray-dried lipid particles coformulated with immunoglobulin and loaded with a prototype vaccine," Pharm. Res., p. 971-979,		

Examiner Signature	David A. Samuels	Date Considered	2/5/04
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449A/PTO

(use as many sheets as necessary)

Sheet	1	of	1
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Complete if Known

Application Number	09/919,477
Filing Date	07/30/2001
First Named Inventor	Adrian Bot et al.
Art Unit	1614
Examiner Name	Unassigned
Attorney Docket Number	0157.00

U.S. PATENT DOCUMENTS

[illegible]

FOREIGN PATENT DOCUMENTS

Examiner Initials*	Cite No.¹	Foreign Patent Document		Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T
		Country Code³	-Number⁴ -Kind Code⁵ (if known)				
LW	AA	WO	00/00215	01/06/2000	ALLIANCE		
	AB	WO	96/40066	12/19/96	UNIV. OF ALBERTA		
	AC	WO	99/09956	03/04/1999	CORIXA CORP.		
	AD	WO	98/31346	07/23/1998	MA. INSTITUTE TECH		
	AE	WO	00/56282	09/28/2000	SEC. STATE DEFENCE		
	AF	WO	01/64254	09/07/2001	ALLIANCE PHARMACEU		
	AG	WO	01/85137	11/15/2001	ALLIANCE PHARMACEU		
	AH	EP	0640347	03/01/1995	DAIICHI PHARMACEUT		

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Signature**

David A. Saunders

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FORM PTO-1449
INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.

17945.014

APPLICATION NO.

09/919,477

APPLICANTS

Adrian BOT *et al.*

FILING DATE

July 30, 2001

GROUP

~~1614~~ 1644

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE
<i>duj</i>	AA1	5,985,309	11/1999	Edwards <i>et al.</i>	<u> </u>	<u> </u>	
	AB1						
	AC1						
	AD1						
	AE1						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION
<i>duj</i>	AF1	88/01862	3/1988	PCT	<u> </u>	<u> </u>	Yes No
	AG1						Yes No
	AH1						Yes No
	AI1						Yes No
	AJ1						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

<i>duj</i>	AK	1	International Search Report, PCT/US02/13145, issued August 20, 2002				
	AL	1					
	AM	1					
	AN	1					
	AO	1					
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